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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 08/862,442      | 05/23/1997  | ANDREW W. SHYJAN     | 07334/004002        | 3446             |

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FISH & RICHARDSON PC  
225 FRANKLIN ST  
BOSTON, MA 02110

EXAMINER

CANELLA, KAREN A

| ART UNIT | PAPER NUMBER |
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1642

DATE MAILED: 07/18/2003

40

Please find below and/or attached an Office communication concerning this application or proceeding.

|  |   |                               |   |  |  |  |   |   |  |
|--|---|-------------------------------|---|--|--|--|---|---|--|
| <b>Office Action Summary</b>   | Application No.<br><b>08/862,442</b>  | Applicant(s)<br><b>Shyjan</b> |   |  |  |  |   |   |  |
|  | Examiner<br><b>Karen Canella</b>  | Art Unit<br><b>1642</b>       |  |  |  |  |   |   |  |
| -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  |   |                               |   |  |  |  |   |   |  |
| <b>Period for Reply</b><br>A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE <u>3 months</u> MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION. <ul style="list-style-type: none"> <li>- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.</li> <li>- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.</li> <li>- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.</li> <li>- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).</li> <li>- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).</li> </ul> |   |                               |   |  |  |  |   |   |  |
| <b>Status</b> <p>1) <input type="checkbox"/> Responsive to communication(s) filed on _____</p> <p>2a) <input type="checkbox"/> This action is FINAL.      2b) <input checked="" type="checkbox"/> This action is non-final.</p> <p>3) <input type="checkbox"/> Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i>, 1935 C.D. 11; 453 O.G. 213.</p>  |   |                               |   |  |  |  |   |   |  |
| <b>Disposition of Claims</b> <p>4) <input checked="" type="checkbox"/> Claim(s) <u>29, 31-38, 43, and 45-56</u> is/are pending in the application.</p> <p>4a) Of the above, claim(s) _____ is/are withdrawn from consideration.</p> <p>5) <input checked="" type="checkbox"/> Claim(s) <u>29 and 31-38</u> is/are allowed.</p> <p>6) <input checked="" type="checkbox"/> Claim(s) <u>43 and 45-56</u> is/are rejected.</p> <p>7) <input type="checkbox"/> Claim(s) _____ is/are objected to.</p> <p>8) <input type="checkbox"/> Claims _____ are subject to restriction and/or election requirement.</p>   |   |                               |   |  |  |  |   |   |  |
| <b>Application Papers</b> <p>9) <input type="checkbox"/> The specification is objected to by the Examiner.</p> <p>10) <input type="checkbox"/> The drawing(s) filed on _____ is/are a) <input type="checkbox"/> accepted or b) <input type="checkbox"/> objected to by the Examiner.<br/>Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).</p> <p>11) <input type="checkbox"/> The proposed drawing correction filed on _____ is: a) <input type="checkbox"/> approved b) <input type="checkbox"/> disapproved by the Examiner.<br/>If approved, corrected drawings are required in reply to this Office action.</p> <p>12) <input type="checkbox"/> The oath or declaration is objected to by the Examiner.</p>   |   |                               |   |  |  |  |   |   |  |
| <b>Priority under 35 U.S.C. §§ 119 and 120</b> <p>13) <input type="checkbox"/> Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).</p> <p>a) <input type="checkbox"/> All b) <input type="checkbox"/> Some* c) <input type="checkbox"/> None of:</p> <ol style="list-style-type: none"> <li>1. <input type="checkbox"/> Certified copies of the priority documents have been received.</li> <li>2. <input type="checkbox"/> Certified copies of the priority documents have been received in Application No. _____.</li> <li>3. <input type="checkbox"/> Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).</li> </ol>  |   |                               |   |  |  |  |   |   |  |
| <p>*See the attached detailed Office action for a list of the certified copies not received.</p> <p>14) <input type="checkbox"/> Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).</p> <p>a) <input type="checkbox"/> The translation of the foreign language provisional application has been received.</p> <p>15) <input type="checkbox"/> Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.</p>  |   |                               |   |  |  |  |   |   |  |
| <b>Attachment(s)</b> <table style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 50%; padding: 2px;">1) <input type="checkbox"/> Notice of References Cited (PTO-892)</td> <td style="width: 50%; padding: 2px;">4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____</td> </tr> <tr> <td style="width: 50%; padding: 2px;">2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)</td> <td style="width: 50%; padding: 2px;">5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)</td> </tr> <tr> <td style="width: 50%; padding: 2px;">3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____</td> <td style="width: 50%; padding: 2px;">6) <input type="checkbox"/> Other: _____</td> </tr> </table>   |   |                               |   | 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ | 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) | 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ | 6) <input type="checkbox"/> Other: _____ |
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| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |                               |   |  |  |  |   |   |  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____  | 6) <input type="checkbox"/> Other: _____                                    |                               |   |  |  |  |   |   |  |

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### **DETAILED ACTION**

1. The finality of the Office action of Paper No. 37, mailed May 29, 2002, is withdrawn in light of the amendment filed May 22, 2002.
2. Claims 39-42 have been canceled. Claims 43 and 51 have been amended. Claims 29, 31-38, 43 and 45-56 are pending and under consideration.
3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.
  
4. The rejection of claims 29, 31-38, 43 and 45-56 under 35 U.S.C. 101 and 35 U.S.C. 112, first paragraph, because the claimed invention is not supported by either a specific, substantial asserted utility or a well established utility is withdrawn in light of applicants arguments.
5. The rejection of claims 37, 38, 43 and 45-56 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention is withdrawn in light of applicants amendments.

#### ***New Grounds of Rejection***

6. Claims 43 and 45-56 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for polypeptides encoded by nucleic acids which hybridize to the complement of the nucleic acid molecules of SEQ ID NO:2, 6, 8, the cDNA contained in the clones of NRRL-Deposit No. B-21426, ATCC Accession No. 97880 and ATCC Accession No. 97881, at 68 degrees C in 0.1 X SSC, at 0.1% SDS, does not reasonably provide enablement for polypeptides encoded by nucleic acids which hybridize to the nucleic acid molecules of SEQ ID NO:2, 6, 8, the cDNA contained in the clones of NRRL-Deposit No. B-21426, ATCC Accession No. 97880 and ATCC Accession No. 97881 at 68 degrees C in 0.1 X SSC, at 0.1% SDS. The

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specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The claims are drawn in part to nucleic acid molecules which hybridize to the nucleic acid molecules of SEQ ID NO:2, 6, 8, the cDNA contained in the clone of NRRL-Deposit No. B-21426, ATCC Accession No. 97880 and ATCC Accession No. 97881. It is noted that only the nucleic acids which hybridize to the complements of the nucleic acid molecules of SEQ ID NO:2, 6, 8, the cDNA contained in the clone of NRRL-Deposit No. B-21426, ATCC Accession No. 97880 and ATCC Accession No. 97881 would encode a protein having the tumor suppressor characteristics of the disclosed proteins. The proteins encoded from the nucleic acids which hybridize directly to the claimed nucleic acids would not be expected to have any of the same amino acid sequence of the polypeptides encoded by the disclosed nucleic acids. The specification does not teach how to use such variant peptides. Therefore, one of skill in the art would be subject to undue experimentation in order to use the broadly claimed polypeptides.

7. Claims 51-56 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection. Claims 50-56 are drawn to an isolated polypeptide encoded by a nucleic acid molecule that comprises at least 30 nucleotides and hybridizes to the nucleic acid molecules of SEQ ID NO:2, 6, 8, the cDNA contained in the clones of NRRL-Deposit No. B-21426, ATCC Accession No. 97880 and ATCC Accession No. 97881, at 68 degrees C in 0.1 X SSC, at 0.1% SDS, and the complements of said nucleic acids. The specification as filed contemplates a 30 nucleotides fragment for the disclosed nucleic acids for use in diagnostic methods (page 106, lines 1-10). This disclosure does not provide support for the instant claims drawn to a polynucleotide encoded by a nucleic acid which minimally comprises 30 nucleotides and hybridizes to the disclosed nucleic acids or the complements

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thereof because use of a 30-mer oligonucleotide as a probe has no nexus to the translation of said probe into a polypeptide having the characteristic of the disclosed proteins.

8. All other rejections and objections as set forth in Paper No. 37 are withdrawn.

***Conclusion***

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen Canella whose telephone number is (703) 308-8362. The examiner can normally be reached on Monday through Friday from 8:30 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, can be reached on (703) 308-3995. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

  
Karen A. Canella, Ph.D.

Patent Examiner, Group 1642

July 17, 2003